

CLAIMS

1. A pharmaceutical formulation comprising: (a) an effective amount of levothyroxine sodium, (b) microcrystalline cellulose which has a mean particle size of less than 125µm and is present in an amount of 60 to 85% w/w based upon the total weight of the formulation, and (c) pregelatinised starch present in an amount of 5 to 30% w/w based upon total weight of the formulation.
2. A pharmaceutical formulation as claimed in claim 1 wherein the microcrystalline cellulose has a mean particle size less than or equal to 100µm.
3. A pharmaceutical formulation as claimed in claim 1 or claim 2 wherein the ratio of microcrystalline cellulose:pregelatinised starch is in the range of 2:1 to 15:1.
4. A pharmaceutical composition as claimed in any one of claims 1-3 wherein the microcrystalline cellulose and pregelatinised starch comprise water which is present in an amount 3-6% w/w based on the total weight of the formulation.
5. A pharmaceutical formulation as claimed in any one of claims 1-4 wherein the levothyroxine sodium is hydrated.
6. A pharmaceutical formulation as claimed in claim 5 wherein the levothyroxine sodium is the pentahydrate form.
7. A pharmaceutical formulation as claimed in any one of claims 1-6 which further comprises one or more glidant/lubricants.
8. A pharmaceutical formulation as claimed in claim 7 wherein the glidant/lubricants are selected from: colloidal anhydrous silica, talc and/or magnesium stearate.
9. A pharmaceutical formulation as claimed in any one of claims 1-8 which is stable to the extent that potency decreases by less than 5% when the pharmaceutical formulation is stored at 25°C and 60% relative humidity for 12 months.
10. A pharmaceutical formulation as claimed in any of claims 1-9 in unit dose form.
11. A pharmaceutical formulation as claimed in claim 10 wherein the unit dose form is a tablet.
12. A pharmaceutical formulation as claimed in any of claims 1-11 for use in medical therapy.

13. A pharmaceutical formulation as claimed in any of claims 1-11 for use in the treatment of thyroid hormone disorders in a mammal, such as man.

5 14. Use of a pharmaceutical formulation as claimed in any of claims 1-11 in the manufacture of a medicament for the treatment of thyroid hormone disorders in a mammal such as man.

10 15. A method of treating thyroid hormone disorders comprising administering a pharmaceutical formulation as claimed in any of claims 1-11.

15 16. A process for preparing a pharmaceutical formulation as claimed in any of claims 1-11 comprising (a) preparing a triturate of levothyroxine sodium, (b) mixing the triturate with the remaining components of the pharmaceutical formulation, and (c) compression.

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